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Teva Pharmaceuticals USA, Inc.

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff,

v.

CORCEPT THERAPEUTICS, INC., AND OPTIME CARE INC.,

Defendants.

Case No. 5:24-cv-03567-NW

PLAINTIFF TEVA PHARMACEUTICALS USA, INC.'S SUPPLEMENTAL BRIEF REGARDING STATUTE OF LIMITATIONS IN OPPOSITION TO DEFENDANTS CORCEPT THERAPEUTICS, INC.'S, AND OPTIME CARE INC.'S, MOTION TO DISMISS

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Teva's entire lawsuit is timely for multiple independent reasons. The Court can and should reject all of Defendants' statute of limitations arguments now.

I. THE "CONTINUING VIOLATIONS" RULE MAKES TEVA'S CLAIMS TIMELY.

The key precedent for the "continuing violations" doctrine is the Ninth Circuit's decision in *Samsung Elecs. Co. v. Panasonic Corp.*, 747 F.3d 1199 (9th Cir. 2014). Although Teva has repeatedly cited *Samsung*, *e.g.*, Teva MTD Opp. 18-20, 22-23, 28, Defendants have never addressed it even once in connection with the "continuing violations" doctrine in any of their submissions. Under the "continuing violations" doctrine, an antitrust plaintiff can challenge conduct that occurred more than four years before the complaint was filed, so long as the plaintiff alleges the defendant took an "overt act" within the past four years that (1) was "new and independent" of the original act, and (2) inflicted "new and accumulating injury" on the plaintiff. *Id.* at 1202. *Samsung* allowed a plaintiff to challenge an agreement the defendants entered seven years before the suit was filed. *Id.* at 1203-04. It cited other Ninth Circuit cases allowing antitrust plaintiffs to challenge conduct that occurred as many as 18 years before they filed suit. *Id.* at 1203. Defendants are thus flatly wrong to suggest an antitrust plaintiff can never challenge conduct that occurred more than four years before filing suit. And here, Teva's allegations make clear that the "continuing violations" doctrine renders all of its claims timely.

Exclusive Dealing: Teva's exclusive dealing claim is timely under the "continuing violations" doctrine for three independent reasons. First, Defendants amended their agreement at least three times during the limitations period—twice in 2022, and a comprehensive amendment in 2024, each time adjusting the agreement's terms. (¶¶138, 143 & n.11.) *Samsung* holds that "[t]he typical antitrust continuing violation occurs … when conspirators continue to meet to fine-tune their cartel agreement." *Samsung*, 747 F.3d at 1204. That is what Teva alleges here. Defendants try to skirt this principle on the grounds that "the exclusivity term [Teva] challenges has remained 'in place' since 2017 and was subject to 'automatic renewal on three-year terms.'" (Def. Br. 5.) But Defendants did not just allow their agreement to auto-renew on identical terms; instead, they *amended and restated* the agreement, repeatedly "fine-tun[ing]" it, which is all "continuing violations" requires. *Id.* at 1204. And, as *Samsung* makes clear, it does not matter that all versions of the agreement imposed an exclusivity term. In *Samsung*, the plaintiff filed suit in 2010, alleging that a licensing agreement was

anticompetitive. *Id.* at 1201-02. The defendants had first entered the agreement in 2003 and amended it in 2006. *Id.* The 2006 amendment "contained the same 6 percent royalty terms" the plaintiff alleged were anticompetitive, *id.* at 1202, but that did not matter, *id.* at 1203-04. The fact that the defendants "continue[d] to meet to fine-tune" their agreement was enough to allow the plaintiff to challenge both the 2003 and the 2006 versions of the agreement, even in 2010. *Id.* The same is true here.[1]

Second, Defendants restarted the clock when they enforced their agreement against Teva in May 2024, by invoking it to block Teva from distributing its product through Optime. (¶139.) Defendants ignore this argument, but the Ninth Circuit has "repeatedly held that acts taken to enforce a contract were overt acts that restarted the statute of limitations," *Samsung*, 747 F.3d at 1204, "so long as the defendant had the ability not to take the challenged action, even if that would have required breaching the allegedly anti-competitive contract," *id.* at 1203. For example, "a power producer's refusal to wheel electricity in accordance with a pre-limitations contract constituted an overt act that restarted the statute of limitations. Even though the anticompetitive agreement to divide the market between producers dated back to 1972, the anti-competitive acts of the parties to that agreement, taken pursuant to its terms, were sufficient to support an antitrust action 18 years later." *Id.* Optime's May 2024 refusal to distribute Teva's product is exactly the same and thus likewise restarted the clock.

Third, Defendants restarted the clock on Teva's exclusive dealing claim every time they steered prescriptions to Optime, and away from Teva, which they did throughout the limitations period, and continue to do to this day. (*E.g.*, ¶¶150-56, 161-66, 167-87.) Defendants ignore this argument, too. But *Samsung* cited the example of "an arrangement in which a tourism company agreed to steer customers to preferred souvenir shops. We held that a cause of action accrued each and every time that a tourist was shepherded away from the plaintiff's non-preferred shop … even though the agreement predated the limitations period." 747 F.3d at 1203. The same analysis applies here.

Orange Book and Sham Litigation: Teva's Orange Book and sham litigation claims are

[1] Defendants also say Teva needed to allege "distinct injuries" that "arise from" the amendments. (Def. Br. 5.) *Samsung* requires no such thing, and Defendants cite no authority. Regardless, Teva alleged that the April 2024 amendment heightened the antitrust concerns with Defendants' agreement by allowing Corcept to render the agreement non-exclusive as to itself, while denying Optime a similar right. (¶143 & n.111.) That change made even more clear that the agreement is a coercive effort by Corcept to use its monopoly power to stifle competition. *See* Teva MTD Opp. at 16.

timely under the "continuing violations" doctrine because both of *Samsung*'s steps are satisfied based on Corcept's assertion of the '800 and '801 patents in March 2023 (¶117), and also based on Defendants' actions related to exclusive dealing and physician kickbacks since June 2020.

Step One is satisfied because these acts were all "new and independent" acts compared to the Orange Book fraud and pre-2020 sham litigations, because nothing about committing Orange Book fraud or bringing sham litigations requires entering into anticompetitive exclusive dealing agreements, asserting additional sham patent claims, or making illicit payments to physicians. *Samsung*, 747 F.3d at 1202 ("new and independent act" means one "that is not merely a reaffirmation of a previous act").

Step Two is satisfied because these anticompetitive acts all work together to inflict "new and accumulating injury" on top of each other. *Id.* at 1203-04. The injuries from exclusive dealing, additional sham litigations, and physician payments are "new" compared to the injuries from Orange Book fraud and earlier sham litigations. They occurred later in time, and they are distinct in character. Exclusive dealing and physician payments injure Teva by preventing Teva from gaining market share when it is on the market. (*E.g.*, ¶¶123-66, 167-87.) Whereas Orange Book fraud and sham litigations injured Teva by delaying its ability to enter the market in the first place. (*E.g.*, ¶¶82-114, 115-22.) And the injuries are "accumulating" in that they all contribute to Teva's lost profits in the Korlym market, and they are part of one overarching scheme to artificially preserve Corcept's monopoly. (*E.g.*, ¶¶1, 4, 5, 6, 9, 10, 57, 203, 215, 217, 218, 222.) Under *Samsung*, the "continuing violations" doctrine allows Teva to challenge all of the facets of this scheme together.

Defendants have no good answer to this argument, instead claiming that an act related to one antitrust "theory" cannot serve as an "overt act" for acts related to other antitrust theories. (Def. Br. 1, 3.) But first, this argument does not address Corcept's assertion of the '800 and '801 patents in March 2023. And more importantly, this argument has zero support. *Samsung* imposes no such requirement. On the contrary, *Samsung* cited *Pace Indus., Inc. v. Three Phoenix Co.*, 813 F.2d 234 (9th Cir. 1987), as an example of a case in which the Ninth Circuit held that filing a lawsuit to enforce an illegal contract (akin to filing a sham litigation) counts as an "overt act" sufficient to restart the clock on a lawsuit challenging the underlying contract as an illegal restraint of trade. *Samsung*, 747 F.3d at 1203. In other words, an act that triggers a claim under one "theory" of antitrust liability can

serve as an overt act that restarts the clock on a claim that asserts a different, but related, theory of antitrust liability. More broadly, as the seminal Areeda treatise explains, "[w]hen the monopolist creates its monopoly by a series of repeated or reasserted acts designed to maintain its monopoly, the statute of limitation is restarted provided that the subsequent acts fall within the definition of 'independent' predicate acts." Areeda & Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶320c4. There is no question that exclusive dealing, Orange Book fraud, sham litigations, and physician kickbacks are all "independent" of each other, nor that they all work together to "maintain [Corcept's] monopoly," inflicting new and accumulating injury on Teva. *Id.* That distinguishes Defendants' cases, which all held that the "continuing violations" doctrine was unavailable because, unlike here, plaintiffs could not point to any acts within the limitations period that caused them new and accumulating harm; rather, all of the harm they suffered was inflicted by the defendants' original acts. *See Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 190 (1997) ("[Plaintiffs] have not shown how any new act could have caused them harm over and above the harm that the earlier acts caused"); *Stanislaus Food Prod. Co. v. USS-POSCO Indus.*, 2010 WL 3521979, at *17 (E.D. Cal. Sept. 3, 2010) ("the injury was complete" at the time of contract formation); *Arcell v. Google LLC*, 2023 WL 5336865, at *5 (N.D. Cal. Aug. 18, 2023) (similar). That Defendants' scheme implicates multiple strands of antitrust law is reason to condemn it, not to shield it from challenge.

Physician Kickbacks: All of Corcept's illicit physician payments are similarly actionable because each one restarted the clock on the entire illicit payment scheme. *Samsung*, 747 F.3d at 1203.

II. THE "SPECULATIVE DAMAGES" RULE MAKES TEVA'S CLAIMS TIMELY.

In addition to (and independent of) the above, *Samsung* holds that if a plaintiff is "not in the [relevant] market"—and if the parties could not "have known for certain whether [the plaintiff] would enter that market"—then an antitrust claim is too speculative, and the plaintiff can wait to file suit until it enters the market. 747 F.3d at 1204-05. The Ninth Circuit reaffirmed that holding in *Oliver v. SD-3C LLC*, 751 F.3d 1081, 1087 (9th Cir. 2014), which Defendants also ignore. Until Teva had FDA approval in August 2020 (¶77), nobody could have known for certain whether Teva would have been able to enter the market, because FDA approval is never guaranteed, not even when an ANDA has tentative approval—as Teva explained in its Complaint (¶46). Under *Samsung* and *Oliver*, that means

it would have been too speculative for Teva to bring any of its claims until August 2020 at the earliest, and Teva was entitled to wait until it was actually on the market, in January 2024, before filing suit.

Defendants assert that this argument is "unpled" and thus waived. (Def. Br. 3.) That is wrong. A plaintiff's burden is to "allege[] sufficient *facts* to show that" an exception to the statute of limitations applies. *Smith v. eBay Corp.*, 2012 WL 27718, at *5 (N.D. Cal., Jan. 5, 2012) (emphasis added). Under *Samsung* and *Oliver*, Teva has alleged sufficient facts to trigger the "speculative damages" exception, because Teva alleged that it was not in the market until January 2024 (¶123), and that the parties could not have known whether it would enter the market until August 2020 at the earliest, when it received FDA approval (¶¶46, 77). That distinguishes the unpublished Third Circuit case cited by Defendants, which expressly noted that the plaintiff's complaint contained nothing to suggest there was uncertainty about whether the FDA would grant approval. *Cf. Perrigo Co. v. AbbVie Inc.*, 2022 WL 2870152, at *5 n.12 (3d Cir. July 21, 2022). No additional allegations were necessary.

III. THE TIMING OF TEVA'S FDA APPROVAL MAKES ITS CLAIMS TIMELY.

All of Teva's claims are also timely for the independent reason that Teva lacked FDA approval until August 2020, and was thus legally forbidden to sell generic Korlym before then. (¶¶45, 77.) It is well established that a pharmaceutical company lacks standing "[t]o state *any* substantive antitrust claim" if it is "excluded from the market because it lacks FDA approval." *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 2009 WL 10674453, at *2-3 (C.D. Cal. May 15, 2009) (emphasis added); Teva MTD Opp. 17-18 (collecting cases). Defendants respond that there is a narrow exception where a pharmaceutical company lacking FDA approval may be able to bring certain antitrust claims if it can allege its "intent and preparedness" to enter the market, and Defendants say Teva had such intent and preparedness in 2018 or 2019. (Def. Br. 4.) But Teva does not allege that it *was* prepared to enter the market in 2018 or 2019; rather, Teva alleges it *would have been* prepared to do so in the but-for world, if Defendants had not violated the antitrust laws. (¶¶79-80, 204.) The "intent and preparedness" exception is therefore inapplicable, and Teva had no cause of action before receiving FDA approval.[2]

[2] Defendants also cite *Aventis*, but *Aventis* held that *even if* the plaintiff had "satisfie[d] the intent-and-preparedness test," the plaintiff *still* would have lacked a cause of action because "the FDA could yet decline to approve [its] application," which meant "causation on some potential damages … would still be speculative." 2009 WL 10674453, at *4. The same was true of Teva's application (¶46), which confirms that Teva could not have sued for damages before it obtained FDA approval.

Dated: August 11, 2025

Respectfully submitted,

By: */s/ Devora W. Allon*

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FILER'S ATTESTATION

Pursuant to Civil L.R. 5-1(i)(3), regarding signatures, I, Devora Allon, attest that concurrence in the filing of this document has been obtained.

/s/ Devora W. Allon
Devora W. Allon

CERTIFICATE OF SERVICE

I hereby certify that on August 11, 2025, I caused to be filed the foregoing document with the United States District Court for the Northern District of California using the CM/ECF system and caused it to be served on all registered participants via notice of electronic filing.

/s/ Devora W. Allon
Devora W. Allon